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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/371,648	08/10/99	YANAGIMACHI R	265036600070

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BARBARA E ARNDT
JONES DAY REAVIS & POGUE
NORTH POINT
901 LAKESIDE AVENUE
CLEVELAND OH 44114

EXAMINER	
PARAS JR,P	
ART UNIT	**PAPER NUMBER**
1632	15

DATE MAILED: 02/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/371,648	YANAGIMACHI, RYUZO	
	Examiner	Art Unit	
	Peter Paras	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

Applicants' Amendment filed on November 27, 2000 (Paper No. 14) has been entered. Claims 1-3 and 21 have been amended. Claims 1-8 and 10-21 are pending and are under current examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 10-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lavitrano et al taken with Kuretake et al. The prior rejection of claims 1-8 and 10-21 under 35 U.S.C. 103(a) is maintained for the reasons of record advanced in Paper No. 12, on pages 1-5 of the Office Action.

Applicants argue that neither Lavitrano nor Kuretake, alone or in combination, teach or suggest the present invention, as recited in the amended claims. Particularly since Lavitrano suggest only that living sperm cells are able to take up DNA and that Lavitrano do not suggest the use of membrane disrupted or demembranated sperm heads for transferring DNA into an oocyte. Applicants argue that Kuretake does not remedy the defects of Lavitrano, particularly because Kuretake does not teach or suggest preincubation of membrane disrupted or demembranated sperm heads with exogenous nucleic acid, or that transgenic embryos can be obtained by this method. Applicants argue that the Examiner has misunderstood Applicants' arguments

presented in the Amendment filed on July 11, 2000 with regard to use of live sperm as vectors to transfer DNA. Finally, Applicants assert that the prior art teaches away from employing dead sperm as vectors for transferring DNA. See pages 3-5 of the Amendment.

In response, the Examiner maintains that Applicant's arguments have been considered, however, are not persuasive for the reasons of record and as discussed herein. The Examiner maintains that both "live" and "dead" sperm are functionally equivalent with regard to the ability to fertilize oocytes. Also "live" and "dead" sperm are able to transfer DNA into an unfertilized oocyte to create a transgenic non-human animal while simultaneously fertilizing the same unfertilized oocyte. Since it has been established that both "live" and "dead" sperm are functionally equivalent and that transgenesis must occur at fertilization when using sperm as vectors for DNA transfer, then it is clear that a means of **increasing the rate of fertilization would also increase the rate of transgenesis**. The basis for preferential use of sperm having a damaged plasma membrane (or dead sperm as defined by the specification, see Office Action page 3) has been provided by Kuretake et al who disclose that sperm with a damaged plasma membrane increase the fertilization rate by ICSI (page 789, paragraph 2, lines 5-6). Additionally, Applicants' use the argument that the success of transgenesis via live sperm DNA transfer correlates to successful transgenesis by a method which relies upon membrane-disrupted or demembranated sperm heads for DNA transfer (see amendment page 5, lines 14-17) and rely on references (on page 4 of the amendment) for support that discuss methods of DNA transfer using live or intact

sperm. See Office Action pages 1-5, particularly pages 3-4. Applicants have not addressed the issue of whether or not an **increase in the rate of fertilization would also increase the rate of transgenesis** as motivation for combining Lavitrano and Kuretake. Finally, with regard to Applicants' assertion that Lavitrano taught that "only live sperm can take up DNA", the Examiner would like to point out that Lavitrano also taught that foreign DNA can be transferred into egg cells at fertilization via sperm (see Discussion, page 721, 1st paragraph.) thereby supporting the Examiner's position that a correlation exists between fertilization and transgenesis. Therefore, an increase in the rate of fertilization, as taught by Kuretake, would also increase the rate of transgenesis.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Kay Pinckney whose telephone number is (703) 305-3553.

Peter Paras, Jr.

Art Unit 1632

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER